News from Ed Markey

United States Congress Massachusetts Seventh District

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CONTACT: Tara McGuinness
Katharine Reinhalter
(202) 225-2836

FDA INTERNAL REPORT REVEALS THAT COMPANIES FAIL TO COMPLETE REQUIRED SAFETY AND EFFECTIVENESS STUDIES FOR MEDICAL DEVICES

Rep. Markey Investigates Company Reporting with the FDA

Washington, DC: Representative Edward J. Markey (D-MA), a Senior Member of the Energy and Commerce Committee, sent a letter to the Food and Drug Administration (FDA) today requesting more information about the expedited approval process for medical devices. Last week, Rep. Markey released a report revealing that the majority of pharmaceutical companies benefiting from the FDA's "accelerated approval" process, a mechanism designed to expedite drugs for patients with life-threatening illnesses, have not conducted the post-marketing studies that are required by law on a timely basis. An internal FDA report reveals that the expedited approval process for class III medical devices has very similar problems leaving patients in the dark about critical information about the safety and effectiveness of the devices.

"It appears that drug companies are not the only ones that are dragging their feet when it comes to postmarketing studies, device companies are also guilty of delaying, stretching out or even submitting fraudulent data to avoid completing these important safety and effectiveness studies. The public has a right to know which device companies are not completing their studies on a timely basis," said Rep. Markey.

On March 18, 2005, the FDA's Center for Devices and Radiological Health (CDRH) released a report, examining the expedited approval process for class III medical devices. The FDA report concluded that companies are not complying with FDA mandates to complete postmarketing studies as a condition of approval and raised questions about the FDA's ability to enforce company compliance. Further, the report noted that the FDA "Staff was unable to retrieve any information for the majority (58%) of [Premarket Applications]."

"This is not like losing your car keys, this misplaced information includes key data about the safety and effectiveness of medical devices. It is completely unacceptable for the FDA to misplace or lose track of this important information. The FDA needs to have a system in place to ensure that important safety and effectiveness studies are completed on a timely basis."

Rep. Markey's letter asks the FDA to identify the companies that are responsible for the condition of approval studies listed in the report, explain what actions the FDA is conducting to ensure that

companies do not submit fraudulent data and conduct studies on a timely basis, and explain what steps the FDA is taking to keep track of these important studies.

For more information on Rep. Markey's report on the accelerated approval process for drugs or his work on FDA issues please visit http://www.house.gov/markey/ The FDA's Center for Devices and Radiological Health (CDRH) report may be found at http://www.fda.gov/oc/whitepapers/epi_rep.pdf.

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